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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,634	01/20/2004	Gregory E. Sancioff	D0188.70165US02	8269

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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02/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/760,634	SANCOFF ET AL.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/27/07; 11/02/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/02/2007 has been entered.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 11/02/2007 and 12/27/2007 are considered. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 7-16, 18-35, 37-42, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Atala** (U.S. Patent No. **5,571,119**) in view of **Mericle** (U.S. Patent No. **5,752,964**).

Claims 7, 15, 18, 24-25, 34, 37 and 62: Atala discloses a suturing instrument comprising a handle **72**, a shaft **66** extending from the handle, the shaft having a proximal end near the handle and a distal end opposite the proximal end, the distal end of the shaft having an opening **93** and a passageway **92** constructed and arranged to carry a suture wire **86** to the opening and to plastically deform the suture wire as the suture wire moves through the passageway to cause the suture wire to form a wire suture loop as the suture wire is extended from the opening in the distal end of the shaft, the passageway and the opening being arranged so that the suture wire extends in a generally distal direction upon exiting the opening and may loop back to the distal end of the shaft without requiring additional contact with the instrument, a wire drive **88** adapted to move the suture wire in the passageway, and a cutter adapted to cut the suture wire at a location near the distal end of the shaft. It is noted that the suturing instrument of Atala is adapted to form the claimed wire suture loop, given that the suture material is a (plastically) deformable wire-like material. Also, regarding Claim 62, the steps of driving deformable suture wire through a passageway in a suturing instrument having a distal end, bending the suture wire in the passageway to form a suture wire loop with suture wire that exits the distal end, the suture wire loop formed without requiring further contact of the instrument to form an annular fastener with the suture wire after the suture wire extends from the distal end of the suturing instrument, and

Art Unit: 3734

cutting the suture wire to free the suture wire loop from the instrument encompass the same invention of Claim 7, and therefore Atala's device reads on these limitations (Figures 7-9 and col. 5, lines 41-55, col. 7, lines 51-67, col. 9, lines 43-65).

Atala does not expressly disclose that the cutter moves in the instrument to free the wire suture loop or annular fastener from the instrument, or a cutter including a cutting surface, or bar, adapted to move axially along a shaft of an instrument to cut a suture wire.

Mericle teaches a suturing instrument with a cutter **19** including a cutting surface, or bar, adapted to move axially along a shaft of an instrument to cut the suture wire, which eliminates the need for another instrument such as scissors to cut excess suture material (Figure 4, col. 4, lines 1-28, col. 2, lines 45-51). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a cutter with a cutting surface to move axially along a shaft, as taught by Mericle, to Atala in order to eliminate the need for an additional cutting instrument and offer multi-functionality and simplicity for the surgeon, as well as to reduce the risk of inadvertent cutting of the suture material (col. 4, lines 22-24).

Claims 8 and 26: Atala discloses the wire drive **88** moving the suture wire **86** through the passageway, a free end of the suture wire exiting the opening in the distal end and following an arcuate, or curved, path **92** whereby the free end may loop or lead back toward the instrument (Figures 7-9, col. 9, lines 43-65).

Art Unit: 3734

Claims 9 and 27: Atala discloses the wire drive **88** being adapted to move the suture wire **86** with force sufficient to cause a free end of the suture wire to penetrate tissue (Figures 7-9, col. 9, lines 43-65).

Claims 10 and 28: Atala discloses the cutter being adapted to cut the suture wire so as to form a sharp point on the suture wire (col. 5, lines 41-55).

Claims 11 and 29: Atala discloses the handle having a manually operable actuator adapted to actuate the wire drive (Figures 7-9, col. 7, lines 51-67).

Claims 12 and 30: Atala discloses the cutter being adapted to cut the suture wire to free a portion of the suture wire from the instrument after a length of suture wire is passed through the opening into tissue (col. 5, lines 41-55).

Claims 13 and 32: Atala discloses the suturing instrument being adapted to form the wire suture loop at an extreme axial end of the shaft (Figures 7-9).

Claim 14 and 33: Atala discloses the cutter being adapted to cooperate with a portion of the passageway to cut the suture wire (col. 5, lines 41-55).

Claims 16 and 35: Atala discloses the wire drive being adapted to move the suture wire in an axial direction within the shaft (Figures 7-9, col. 9, lines 43-65).

Claims 19 and 38: Atala discloses a continuous length of suture wire **86**, wherein the instrument is adapted to form a plurality of wire suture loops from the continuous length of suture wire (Figures 7-9).

Claims 20 and 39: Atala discloses the suturing instrument adapted for use in a minimally invasive surgical procedure (col. 3, lines 30-35).

Art Unit: 3734

Claims 21 and 40: Atala discloses the cutter forming part of the passageway (col. 5, lines 41-55).

Claims 22 and 41: Atala discloses the distal end of the shaft including an angled end face (Figures 8-9).

Claims 23 and 42: Atala discloses the suturing instrument arranged to form a wire suture loop in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the passageway such that a free end of the suture wire penetrates the tissue and follows a loop-like trajectory (Figures 7-9).

Claim 31: Atala discloses the suturing instrument adapted to form an approximately circular wire suture loop by suture wire that is driven out of the opening in the distal end (Figures 7-9).

3. Claims 17, 36, and 43-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Atala** (U.S. Patent No. **5,571,119**) and **Mericle** (U.S. Patent No. **5,752,964**), as applied to Claims 7 and 24 above, and further in view of **Gordon** (U.S. Patent No. **5,741,277**).

Claims 17, 36, 43-44: Atala and Mericle disclose the claimed device except for the passageway including an "S" shaped portion that is adapted to deform the suture wire moving through the "S" shaped portion.

Gordon teaches a suturing instrument with a passageway including an "S" shaped portion that is adapted to deform a suture wire moving through the "S" shaped portion (Figures 39, 41A-41C, and col. 26, lines 57-67, col. 27, lines 1-14). It would

Art Unit: 3734

have been obvious to one of ordinary skill in the art at the time of invention to modify Atala and Mericle by providing an "S" shaped portion in the passageway, as taught by Gordon, since it was known in the art that convoluted channels in suturing instruments are used to facilitate forming loops in sutures so as to eliminate the need for an additional looping, knotting instrument.

Claim 45: Atala discloses the wire drive **88** moving the suture wire **86** through the passageway, a free end of the suture wire exiting the opening in the distal end and following an arcuate, or curved, path **92** whereby the free end may loop or lead back toward the instrument (Figures 7-9, col. 9, lines 43-65).

Claim 46: Atala discloses the wire drive **88** being adapted to move the suture wire **86** with force sufficient to cause a free end of the suture wire to penetrate tissue (Figures 7-9, col. 9, lines 43-65).

Claim 47: Atala discloses the cutter being adapted to cut the suture wire so as to form a sharp point on the suture wire (col. 5, lines 41-55).

Claim 48: Atala discloses the handle having a manually operable actuator adapted to actuate the wire drive (Figures 7-9, col. 7, lines 51-67).

Claim 49: Atala discloses the cutter being adapted to cut the suture wire to free a portion of the suture wire from the instrument after a length of suture wire is passed through the opening into tissue (col. 5, lines 41-55).

Claim 50: Atala discloses the suturing instrument adapted to form an approximately circular wire suture loop by suture wire that is driven out of the opening in the distal end (Figures 7-9).

Art Unit: 3734

Claim 51: Atala discloses the suturing instrument being adapted to form the wire suture loop at an extreme axial end of the shaft (Figures 7-9).

Claim 54: Atala discloses the wire drive being adapted to move the suture wire in an axial direction within the shaft (Figures 7-9, col. 9, lines 43-65).

Claim 57: Atala discloses a continuous length of suture wire **86**, wherein the instrument is adapted to form a plurality of wire suture loops from the continuous length of suture wire (Figures 7-9).

Claim 58: Atala discloses the suturing instrument adapted for use in a minimally invasive surgical procedure (col. 3, lines 30-35).

Claim 59: Atala discloses the cutter forming part of the passageway (col. 5, lines 41-55).

Claim 60: Atala discloses the distal end of the shaft including an angled end face (Figures 8-9).

Claim 61: Atala discloses the suturing instrument arranged to form a wire suture loop in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the passageway such that a free end of the suture wire penetrates the tissue and follows a loop-like trajectory (Figures 7-9).

Claim 52-53 and 55-56: Atala and Gordon disclose the claimed device, including an "S" shaped portion of the passageway and the "S" shaped portion including a convex portion and a concave portion (Figures 39, 41A-41C, Gordon), except for the cutter being adapted to cooperate with a portion of the "S" shaped portion of the passageway to cut the suture wire, the cutter including a cutting surface, or bar, adapted to move

axially along a shaft to cut the suture wire, and the cutter including a cutter bar adapted to cut the suture wire at a location between convex and concave portions.

Mericle teaches a cutter being adapted to cooperate with a portion of the "S" shaped portion of the passageway to cut the suture wire, the cutter including a cutting surface, or bar, adapted to move axially along a shaft to cut the suture wire, and the cutter including a cutter bar adapted to cut the suture wire at a location between convex and concave portions (Figure 4, col. 4, lines 1-28, col. 2, lines 45-51). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a cutter with a cutting surface to move axially along a shaft, as taught by Mericle, to Atala and Gordon in order to eliminate the need for an additional cutting instrument and offer multi-functionality and simplicity for the surgeon.

4. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV, hereinafter "**Williamson**", (U.S. Patent No. **5,972,004**) in view of **Mericle** (U.S. Patent No. **5,752,964**).

Claim 63: Williamson discloses a handle, a shaft **42** extending from the handle, the shaft having a proximal end near the handle and a distal end **46** opposite the proximal end, the distal end of the shaft configured for placement against tissue to be sutured without puncturing the tissue ("placed against the patient's tissue"), the distal end having an opening and a passageway to carry a suture wire **10U** to the opening, the passageway being constructed and arranged so that when moved in the passageway, the suture wire exits the opening, enters the tissue to be sutured, and loops back to the

Art Unit: 3734

distal end without requiring additional contact with the instrument (due to the curvature of the distal end of **40**, not as a result of the suture wire being received by “grabber” **50**), a wire drive adapted to move the suture wire in the passageway (Figure 2, col. 12, lines 15-52).

Williamson discloses the claimed device except for a cutter that moves in the instrument to intersect a portion of the passageway and to cut the suture wire at a location near the distal end of the shaft. However, Williamson does disclose a separate cutting tool **60** (col. 14, lines 51-53).

Mericle teaches a suturing instrument with a cutter **19** including a cutting surface, or bar, adapted to move axially along a shaft of an instrument to cut the suture wire, which eliminates the need for another instrument such as scissors to cut excess suture material (Figure 4, col. 4, lines 1-28, col. 2, lines 45-51). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Williamson by providing a cutter with a cutting surface to move axially along the shaft, as taught by Mericle, in order to eliminate the need for a separate cutting tool and offer multi-functionality and simplicity for the surgeon.

Response to Arguments

5. Applicant's arguments filed 11/02/2007 have been fully considered but they are not persuasive.
6. Applicant argues that the device of Atala already has the capability of cutting suture with the blade-like edges of the needle, and therefore one would not be led to

Art Unit: 3734

modify Atala with Mericle. The examiner disagrees. The teaching of having a cutting bar in Mericle would provide the benefit of selectively cutting the suture and therefore reduces the risk of inadvertent cutting of the suture material (col. 4, lines 22-24).

7. In response to applicant's argument that it is unclear how Mericle could be combined with Atala since the curved needle tip of Atala is incompatible with a spatulated tip in Mericle, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Mericle teaches having a cutting bar that would suggest the benefit of selectively cutting suture in the passageway of a needle as disclosed in Atala in order to avoid inadvertent cutting of the suture wire.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER